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(54) Flat, conformable, biomedical electrode.

(57) A biomedical electrode (10) adapted to be applied to a body and adapted to be electrically and mechanically connected to an electrical lead wire (14). The electrode (10) contains a protective, electrically insulative web (12) and an electrically conductive adhesive (20 or 24) adjacent one side of the web (12) which is adapted to be oriented to the body. A release liner (18) is placed between the web (12) and the electrically conductive adhesive (20-24) to facilitate removal and placement of an electrical lead wire (14). The biomedical electrode (10) may have a first layer of pressure sensitive adhesive (16) applied between the web (12) and the release liner (18). A second layer of adhesive (24) which is electrically conductive may be positioned adjacent the release liner (18) opposite from the web (12). An electrically conductive film (22) may be positioned adjacent the second layer of adhesive (24) opposite the release liner and finally a third layer of adhesive (24) which is electrically conductive may be positioned adjacent the electrically conductive film (22) opposite the second layer (24) of conductive adhesive which is adapted to be applied to a body.

Alternatively, a biomedical electrode (10) is provided and is adapted to be applied to a body and adapted to be electrically and mechanically connected to an electrical lead wire (14). The electrode (10) contains a protective, electrically insulative web (12) and an adhesive (16) adjacent one side of the web (12) which is adapted to be oriented to the body. A release liner (18) is placed between the web (12) next to adhesive (16) to facilitate removal and placement of an electrical lead wire (14). An electrically conductive film (22) is positioned adjacent the adhesive (16) opposite the release liner (18). Finally, another layer of adhesive (24) which is electrically conductive is positioned adjacent the electrically conductive film (22) opposite the layer (16) of adhesive, which electrically conductive adhesive (24) is adapted to be applied to a body. Alternatively, the electrode (10) has a metallic coating (34) applied to the bottom side of a protective, electrically insulative web (32). A release liner (18) separates the metallic coating (34) of the protective web (32) from an electrically conductive adhesive (24) which is adapted to be applied to a body.

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Alternatively, the biomedical electrode (110), adapted to be applied to a body (134), has a backing material (116), preferably foam, having an aperture (l20). A protective web (112) at least partially secured to the backing material (116) covers the aperture (120). A removeable liner (118) is positioned between the protective web (112) and the backing material (116). An electrically conductive adhesive (128) is positioned adjacent the backing material (116) on the opposite side from the protective web (112). A second removeable release liner (130) is positioned adjacent the electrically conductive adhesive (128) opposite from the backing material (116). A lead wire (122) having a conductive portion (124) is insertable under the protective web (112) to be secured there upon the removal of the release liner (118), by the protective web (112) and the electrically conductive adhesive (128). A bottom release liner (130) may be removed and the biomedical electrode (110) may be secured to a body (134). The conductive portion (124) of the lead wire (122) should be silver or silver plated and preferably subjected to chloride treatment.

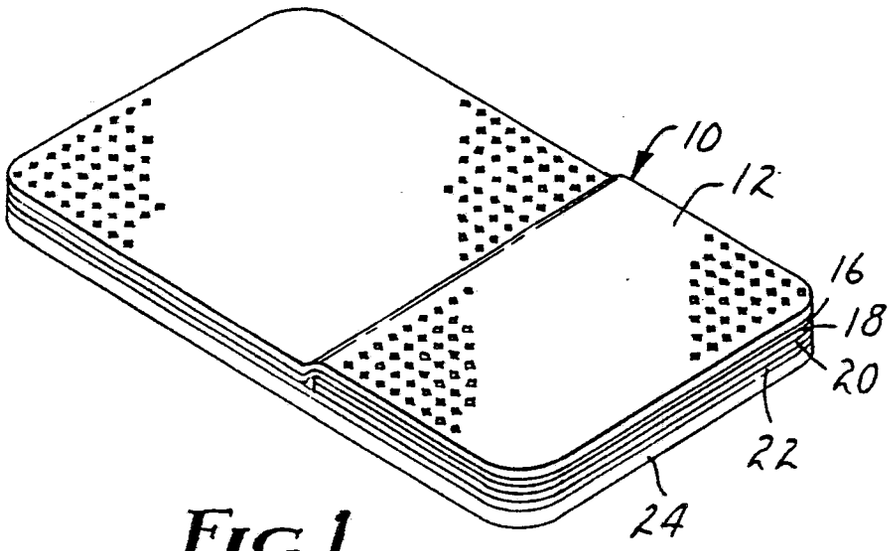

FIG.1

FLAT, CONFORMABLE, BIOMEDICAL ELECTRODE

Technical Field

The present invention relates generally to biomedical electrodes.

Background Art

Biomedical electrodes are useful for both stimulation and body monitoring functions. Stimulation uses of biomedical electrodes include transcutaneous electronic nerve stimulation (TENS) for the treatment of pain and neuromuscular stimulation (NMS) as, for example, treatment for scoliosis. Body monitoring uses for biomedical electrodes include electrocardiogram (ECG) for monitoring hear activity.

Among biomedical electrodes in existence are those of Phipps et al., Cartmell and Larimore. Phipps et al in United States Patent No. 3,170,459 discloses a biomedical instrumentation electrode constructed from multiple plies of discs made from a relatively inflexible material, i.e., cork. The electrode utilizes a conductive gel to establish electrical contact with the body. Cartmell in United States Patent No. 4,543,958 discloses a medical electrode assembly. The electrode has a flexible, dimensionally stable substrate which is striped with an electrically conductive paint. The electrode is then clamped into a bulky cable connector. Larimore in United States Patent No. 4,458,696 (assigned to Minnesota Mining and Manufacturing Company) discloses a TENS electrode with a raised structure to permit entry of and attachment to a tubular electrical conductor.

These electrodes suffer from several deficiencies including that all are "high profile" electrodes and that the electrodes do not "conform" well to the body.

Disclosure of Invention

The present invention provides a biomedical electrode which is (1) flatter and more conformable, (2) has a very low profile, (3) may be trimmed to differing shapes, (4) has flexibility in lead wire insertion direction, and (5) allows the reuse of the lad wire. The electrode of the present invention is flatter and more conformable to body contours and body movement than prior electrodes. The electrode relies on an adhesive contact with a flat electrical conductor as opposed to rubber connector strips or snaps. the electrode has a very low profile which makes it suitable to be worn under tight clothing and to be comfortable when slept upon or when leaned against, as for example, when sitting in a chair. The electrode may be trimmed to virtually any size or shape to allow adaptability in placement and location. The electrode allows for flexibility in lead wire insertion and allows for the lead wire to be inserted from the end of the electrode or from either side. The reuseability of the lead wire leads to economy for use of the biomedical electrode.

The present invention provides a biomedical electrode which is adapted to be applied to a body and adapted to be electrically and mechanically connected to an electrical lead wire. The electrode has a protective, electrically insulative web, an electrically conductive adhesive adjacent one side of the protective, insulative web, that side being adapted to be oriented toward the body, and a release liner between the protective, electrically insulative web and the electrically conductive adhesive. The release liner has a release agent facing the conductive adhesive. The release liner covers only a portion of the surface area of the protective insulative web. In a preferred embodiment, a pressure-sensitive adhesive is located between the release liner and the protective, electrically insulative web. In a preferred embodiment, the protective insulative web is perforated.

In another embodiment, the present invention is a biomedical electrode adapted to be applied to a body. The electrode has a protective, electrically insulative web. The electrode also has an electrically conductive adhesive adjacent one side of the protective insulative web, that side adapted to be oriented toward the body. The electrode contains a removable release liner between the protective, electrically insulative web and the electrically conductive adhesive. The release liner has a release agent facing the conductive adhesive. The release liner covers only a portion of the surface area of the protective, electrically insulative web. The electrode also has an insertable electrical lead wire having an uninsulated portion and an insulated portion. The uninsulated portion of the electrical lead wire is insertable between the

conductive adhesive and said protective, electrically insulative web. At least part of the insulated portion of the electrical lead wire extends beyond an edge of the protective, electrically insulative web. An electrode constructed in this manner provides an electrode in which the removable release liner may be discarded, the insertable electrical lead wire may be positioned and the protective, electrically insulative web may be secured over the insulated portion of the electrical lead wire and secured in place by the electrical conductive adhesive.

The present invention, in another embodiment, provides a biomedical electrode adapted to be applied to a body and adapted to be electrically and mechanically connected to an electrical lead wire. The electrode has a protective, electrically insulated web. The electrode also has a first layer of adhesive adjacent one side of the protective, electrically insulative web that side adapted to be oriented toward the body. The electrode has a release liner adjacent the first layer of adhesive opposite side protective, electrically web. The release liner has a release agent facing the first layer of adhesive the release liner covering only a portion of the surface area of the protective, electrically insulative web. A second layer of electrically conductive adhesive is positioned adjacent the release liner opposite from the protective, electrically insulative web. The electrode also contains an electrically conductive film positioned adjacent the second layer of adhesive opposite said release liner. The electrode further contains a third layer of adhesive which is electrically conductive and positioned adjacent the electrically conductive film opposite the second layer of conductive adhesive and adapted to be applied to the body. In the preferred embodiment, the electrically conductive film is a metallic coating on a self supporting conductive film. In a preferred embodiment, the electrode further has a pressure-sensitive adhesive between the release liner and the protective, electrically insulative web. In another preferred embodiment, the second layer of adhesive contains silver particles.

In another embodiment, the invention provides a biomedical electrode adapted to be applied to a body. The electrode contains a protective, electrically insulative web. The electrode also contains a first layer of adhesive adjacent one side of the protective, electrically insulative web, that side adapted to be oriented toward the body. The electrode contains a removable release liner adjacent the first layer of adhesive opposite from the protective, electrically insulative web the release liner having a release agent facing the first layer of adhesive. The release liner covers only a portion of the surface area of the protective, electrically insulative web. The electrode also contains a second layer of adhesive which is electrically conductive and positioned adjacent the release liner opposite from the protective, electrically insulative web. The electrode also contains an electrically conductive film positioned adjacent the second layer of adhesive opposite the release liner. The electrode also contains a third layer of adhesive which is electrically conductive and positioned adjacent the electrically conductive film opposite the second second layer of adhesive and adapted to be applied to the body. Further, the electrode contains an insertable electrical lead wire having an uninsulated portion and an insulated portion. The uninsulated portion of the electrical lead wire is insertable between the first layer of adhesive and the second layer of adhesive and at least part of the insulated portion of the electrical lead wire extends under the edge of the protective, electrically insulative web. In an electrode constructed in this manner, the removable release liner may be discarded, and insertable electrical lead wire may be positioned and the protective, electrically insulative web may be secured over the uninsulated portion of the electrical lead wire and secured in place by the first layer of adhesive and the second layer of adhesive.

The present invention also provides a biomedical electrode adapted to be applied to a body and adapted to be electrically and mechanically connected to an electrical lead wire. The electrode has a protective, electrically insulated web. The electrode also has a first layer of adhesive adjacent one side of the protective, electrically insulative web that side adapted to be oriented toward the body. The electrode has a release liner adjacent the first layer of adhesive opposite said protective, electrically web. The release liner has a release agent facing the first layer of adhesive the release liner covering only a portion of the surface area of the protective, electrically insulative web. The electrode contains an electrically conductive film positioned adjacent the first layer of adhesive opposite said release liner. The electrode further contains an electrically conductive film positioned adjacent the first layer of adhesive opposite said release liner. The electrode further contains a second layer of adhesive which is electrically conductive and positioned adjacent the electrically conductive film opposite the first layer of conductive adhesive and adapted to be applied to the body. In a preferred embodiment, the electrically conductive film is a metallic coating on a self supporting conductive film.

In an alternative embodiment the invention provides a biomedical electrode adapted to be applied to a body and adapted to be electrically and mechanically connected to an electrical lead wire. The electrode has a top protective, electrically insulative web. An electrically conductive metallic vapor coat is applied to the bottom side of the protective web. A release liner is provided adjacent the metallic vapor coat covering

only a portion of the surface area of the protective web. The electrode further has an electrically conductive adhesive covering the bottom of the electrode covering the release liner in the portion of surface area of the electrode which contains the release liner and covering the metallic film over the remainder of the surface area of the electrode. In a preferred embodiment, the protective web, metallic coating and release liner extend beyond an edge of the electrically conductive adhesive so that the release liner may be easily separated from the electrically conductive adhesive by grasping.

The present invention also provides a biomedical electrode which is adapted to be applied to a body. A backing material is utilized having an aperture a protective web is at least partially secured to the top side of the backing material covering the aperture. A first removable release liner is positioned between the protective web and the backing material. An electrically conductive adhesive is positioned adjacent the bottom side of the backing material covering the aperture in the back material. A second removable release liner is positioned adjacent the electrically conductive adhesive opposite from the backing material. A lead wire is adapted to be positioned from the top side of the backing material within the apertures so as to be adhered by the electrically conductive adhesive. This provides a biomedical electrode in which the second removable liner may be removed and the biomedical electrode may be applied to the body with the electrically conductive adhesive. The first removable release liner may then be removed and the lead wire may be positioned with the electrically conductive end of the lead wire within the aperture and secured by the protective web. In a preferred embodiment, the lead wire is formed with a flattened disc of electrically conductive material and, in one embodiment the flattened disc is silver plated and, in a still another embodiment, has been subjected to chloride treatment. In one embodiment, the backing material is a foam material most preferably a polyethylene foam. In another embodiment, a pressure-sensitive adhesive helps to hold the protective web to the backing material.

Brief Description of Drawings

The foregoing advantages, construction and operation of the present invention will become more readily apparent from the following description and accompanying drawings in which:

Figure 1 is isometric view the biomedical electrode of the present invention.

Figure 2 is a side view of an embodiment of the biomedical electrode of the present invention with a double coated release liner and electrical lead wire illustrated;

Figure 3 is a side view of an embodiment of the biomedical electrode of the present invention with an extended release liner;

Figure 4 is a side view of an embodiment of the biomedical electrode of the present invention with a center located release liner;

Figure 5 is a side view of an embodiment of the biomedical electrode of the present invention with a single sided folded release liner;

Figure 6 is a side view of an embodiment of the biomedical electrode of the present invention with an extended release liner and protective web;

Figure 7 is a side view of an embodiment of the biomedical electrode of the present invention;

Figure 8 is a side view of an alternative embodiment of the biomedical electrode of the present invention;

Figure 9 is an isometric view of the biomedical electrode with the removable release liner being removed and the electrical lead wire being inserted.

Figure 10 is an expanded side view of the biomedical electrode; and

Figure 11 is an isometric view of the biomedical electrode attached to the body.

Detailed Description

Figure 1 illustrates an isometric view of a preferred embodiment view of the biomedical electrode 10 of the present invention. The biomedical electrode 10 is also shown in expanded side view of Figure 2. The top of the biomedical electrode 10 is a protective, electrically insulative web 12. Web 12 protects the top of biomedical electrode 10 from physical damage and covers lead wire 14 when it is inserted in the biomedical electrode 10 to help secure lead wire 14 in place. Web 12 is electrically insulative to confine the electrical signals used in the biomedical electrode to the lead wire 14 or to the body (not shown). As shown

in Figure 1, web 12 is preferably perforated making web 12 more conformable to the body contour and for esthetics. The perforations also assist in the tearability of web 12 once it is desired to remove lead wire 14 from the biomedical electrode 10. In a preferred embodiment, web 12 is approximately 4 mils (1.0 millimeters) thick and is constructed form a pigmented low molecular weight polyethylene film.

Web 12 is attached to the remainder of biomedical electrode 10 with a pressure sensitive adhesive 16. In a preferred embodiment, the pressure sensitive adhesive 16 is an acrylate adhesive. A release liner 18, which is removable, is placed beneath pressure sensitive adhesive 16 covering a portion of the surface area of biomedical electrode 10. Release liner 18 facilitates the lifting of web 12 away from the remainder of the biomedical electrode 10 in order that lead wire 14 may be inserted and web 12 subsequently reapplied securing lead wire 14 in biomedical electrode 10. In a preferred embodiment, release liner 18 is a Polyslick™ material as manufactured by James River Corporation, H.P. Smith Division, Bedford Park, Illinois. A conductive adhesive 20 is positioned in the biomedical electrode 10 below release liner 18. Conductive adhesive 20 need only cover a portion of the surface area of biomedical electrode 10 to which lead wire 14 may be positioned. In a preferred embodiment, conductive adhesive 20 covers approximately the same surface area of biomedical electrode 10 as does release liner 18. This allows for relative general ease in the positioning of lead wire 14 once release liner 18 has been removed. In a preferred embodiment, conductive adhesive 20 is made conductive through the inclusion of silver particles. In a preferred embodiment, a resistivity measurement using a one inch square brass plate above and below the adhesive measures approximately 0.01 ohms. The exact conductivity of conductive adhesive 20, of course, depends upon the end use to which biomedical electrode 10 is intended. Generally, it is expected that resistivities of conductive adhesive may generally range up to one ohm. In another embodiment, approximately ten ohms may be sufficient and higher resistivities may be allowable in other embodiments and for other uses for biomedical electrode 10. Conductive adhesive, especially conductive adhesives containing silver particles are widely available. An example of a suitable adhesive is a solvent based acrylate adhesive containing silver particles about 3 mils (0.76 mm) in diameter which is coated through a knife coater at about 12 mils (3.05 mm) thickness. The coated adhesive is heated to drive off the solvent resulting in an adhesive layer of about 1.0 mils (0.38 mm) in thickness. Note that the silver particles are larger than the thickness of the resulting adhesive giving the layer is needed electrical conductivity. An adhesive similar to this but which has been coated on aluminum is available as X1170 foil tape from Minnesota Mining and Manufacturing Company, St. Paul, Minnesota. Below conductive adhesive 20 an electrically conductive film 22 , preferably a metal vapor coated conductive film, covers a large portion of the surface area of biomedical electrode and, in a preferred embodiment, covers the entire surface of biomedical electrode 10. The purpose of electrically conductive film 22 is to disburse the current delivered by or received by biomedical electrode 10 over a larger portion of the surface area of biomedical electrode 10. Electrically conductive film 22 may also operate to provide an ion barrier between the insertable lead wire 14 and the body. In a preferred embodiment, the electrically conductive film is an ethylene vinyl acetate loaded with approximately 28% carbon or a, Velostat® film manufactured by Minnesota Mining and Manufacturing Company, Saint Paul, Minnesota in either case coated top side with a 7×10^{-8} to 1.2×10^{-7} meters thick vapor coat of aluminum or silver. In a preferred embodiment, electrically conductive film 22 is approximately 3 mils (0.76 millimeters) thick. As indicated, conductive adhesive 24 operates to secure biomedical electrode 10 to the body to biomedical electrode 10 or visa versa. It is preferred that conductive adhesive 24 have better cohesion than adhesion in order to facilitate the ease in which the biomedical electrode 10 may be removed from the body. Conductive adhesive 24 may generally have a volume resistivity of the range from 50 to 200 ohm-centimeters although lower and high volume resistivities may work for some uses of the biomedical electrode 10. In a preferred embodiment, conductive adhesive 24 is from 10 mils (2.5 millimeters) to 60 mils (15.2 millimeters) thick. In a reuseable electrode it is preferred that the conductive adhesive 24 be from 30 mils (7.6 mm) to 44 mils (11.2 mm) thick. In a disposable electrode it is preferred that the conductive adhesive be from 10 mils (2.5 mm) to 24 mils (6.3 mm) thick. An example of a conductive adhesive 24 desirable for a reuseable electrode is described in U.S. patent No. 3,865,770, Blake, Water-Dispersable Pressure-Sensitive Adhesive, Tape Made Therewith, and Novel Tackifiers Therefor, which is hereby incorporated by reference. It is preferred that the adhesive in Blake be modified and the following ingredients used:

Ingredient	Dry Weight Grams	Dry Weight Percent
Copolymer: Butyl Acrylate & Acrylic Acid in 3:1 ratio	83.177	40.945
Glycerin	20	9.8452
Butanediol	20	9.8452
Sorbitol	20	9.8452
Methyl diethanolamine (MDEA)	28	13.783
Potassium Chloride (KCl)	6.9678	3.4300
Foral AX (hydrogenated wood rosin)	25	12.306
Total	203.14	100.04

An example of a conductive adhesive 24 desirable for a disposable electrode is described in U.S. Patent 4,554,924, Engel, Conductive Adhesive and Biomedical Electrode, which is hereby incorporated by reference. It is preferred that the adhesive in Engel be modified and the following ingredients be used:

Ingredient	Dry Weight Grams	Dry Weight Percent
1,4 Butanediol	45	6.3993
Glycerin	75	10.665
Sorbitol	290	41.240
K739, Polyacrylic	17	2.4175
Potassium Hydroxide	3.25	0.46217
Total Water	155	22.042
Acrylic Acid	115	16.354
Irgacure	0.51635	0.07343
Tegbm	2.3186	0.32972
Methyl ethyl hydroquinone	0.12	0.01706
Total	703.20	100.04

Optionally, a second release liner (not shown) may be provided below conductive adhesive 24 to facilitate transportation and storage of biomedical electrode 10 before use or between uses.

Biomedical electrode 10 may be utilized by applying the biomedical electrode 10 to a body being secured by conductive adhesive 24. The protective, electrically insulative web 12 may be lifted since release liner 18 prevents the protective, electrically insulative web 12 from sticking to conductive adhesive 20. Once the protective insulative web 12 is lifted, release liner 18 may be removed and discarded. At this time, lead wire 14 may be inserted so that noninsulated portion 26 of lead wire 14 is positioned over conductive adhesive 20. Lead wire 14 also has an insulative portion 28 which extends from beneath the confines of protective, electrically insulative web 12 and may be connected to suitable electronic equipment intended to utilize biomedical electrode 10. Lead wire 14 may be a copper wire whose insulated portion 28 is insulated with any suitable insulation, as for example, rubber or plastic. The end of noninsulated portion 26 of lead wire 14 is a flat crimped on conductor plate 30. Conductor plate 30 is flat which facilitates the biomedical electrode 10 being of low profile, flat and conformable to the body. Conductor plate 30 may, for example, be a zinc plated copper or, optionally, a silver plated copper with a chloride treatment.

Figure 3 illustrates an alternative embodiment for the biomedical electrode 10A of the present invention. The construction of the biomedical electrode 10A in Figure 3 is similar to the biomedical electrode 10 in Figure 2 except that protective, electrically insulative web 12, pressure sensitive adhesive 16 and release liner 18 extend from one edge of conductive adhesive 20, electrically conductive film 22 and conductive adhesive 24. Having these items extend beyond the edge facilitates the lifting of protective, electrically insulative web 12 in order that release liner 18 may be removed and lead wire 14 inserted.

Figure 4 illustrates another expanded side view of another embodiment of the biomedical electrode 10B of the present invention. The embodiment illustrated in Figure 4 is similar with that as biomedical electrode 10 illustrated in Figure 2 with the exception that the portion of the surface area of biomedical electrode 10 which is covered by release liner 18 and conductive adhesive 20 is positioned centrally in the biomedical electrode 10. This embodiment illustrates that protective insulative web 12, as well as pressure sensitive adhesive 16 may be separated into two portions. Biomedical electrode 10B as illustrated in Figure 4 operates as before, protective insulative web 12 is lifted, release liner 18 is removed and lead wire 14 is inserted over conductive adhesive 20.

In the embodiments of biomedical electrode illustrated in Figures 1-4, a single sheet release liner 18 is illustrated. In these embodiments, release liner 18 is coated both sides with a release agent allowing the release liner 18 to release both from pressure sensitive adhesive 16 and conductive adhesive 20.

Another embodiment of biomedical electrode 10C is illustrated in a side exploded view in Figure 5. The biomedical electrode 10C illustrated in Figure 5 also contains a protective electrically insulative web 12 and a pressure sensitive adhesive 16. The biomedical electrode 10 also contains a release liner 18. Release liner 18 is illustrated as being folded with the closed side fold being positioned interiorly with respect to biomedical electrode 10 and the open side fold being positioned near an edge of the protective, electrically insulative web 12. The release liner 18 as illustrated in Figure 5 may be coated on only one side, the outside of release liner 18 as it is folded so that the release agent still contacts pressure sensitive adhesive 16 and conductive adhesive 24. As in the other embodiments, the biomedical electrode 10 C illustrated in Figure 5 contains conductive adhesive 24 preferably along the entire bottom surface area of biomedical electrode 10. Conductive adhesive 24 is the same as and performs the same purpose as conductive adhesive 24 in Figures 1-4. Note that the biomedical electrode 10C illustrated in Figure 5 is missing electrically conductive adhesive 20 and electrically conductive film 22. As noted earlier, electrically conductive film 22 was used to facilitate the dispersion of electrical currents over the entire surface of biomedical electrode. In situations where such dispersion is not required or such dispersion is not required to be achieved as well as can be achieved with the electrically conductive film 22, the electrically conductive film 22 may be omitted. With the omission of electrically conductive film 22, electrically conductive adhesive 20 is also no longer needed. Electrically conductive adhesive 20 was utilized to secure lead wire 14 when it was positioned within biomedical electrode 10. With the embodiment of the biomedical electrode 10C illustrated in Figure 5 when release liner 18 is removed, lead wire 14 may be inserted in its place and is secured between protective insulative web 12 by pressure sensitive adhesive 15 and conductive adhesive 24.

The biomedical electrode 10D as illustrated in Figure 6 is constructed similarly to the embodiment of biomedical electrode 10C illustrated in Figure 5 with the exception being that protective insulative web 12, pressure sensitive adhesive 15 and release liner 18 extend beyond an edge of conductive adhesive 24 (as in Figure 3) to facilitate lifting of protective insulative web 12 and removal of release liner 18.

The biomedical electrode 10E illustrated in Figure 7 is similar to the biomedical electrode 10 illustrated in Figure 2. Biomedical electrode 10E omits electrically conductive 20 (shown in Figure 2) and since electrically conductive adhesive 20 has been omitted release liner 18 need only be release coated on the side facing adhesive 16. As in Figure 2, the biomedical electrode 10E of Figure 6 has a protective, electrically insulative web 12 which is secured to the remainder of the biomedical electrode 10E with a layer of adhesive 16. It is preferred that layer of adhesive 16 be a pressure sensitive adhesive. As stated above, release liner 18 covers a portion of the surface area of layer of adhesive 16 and is release coated at least on its top side facing layer of adhesive 16. An electrically conductive film 22 is positioned below both adhesive 16 and release liner 18. It is preferred that electrically conductive film be a metallic coated electrically conductive substrate such as an aluminum vapor coat of from 200 to 1200 angstroms thick on a 28% carbon loaded ethylene vinyl acetate substrate. The metallic vapor coat should be on the top side of the electrically conductive film 22 facing said release liner 18. Generally, the electrical resistance over the length of the electrically conductive film should be less than or equal to 1 ohms per inch (0.39 ohms per centimeter) of electrically conductive film 22. An electrically conductive adhesive 24 of the same as described with respect to Figure 2, is than located below electrically conductive film 22 opposite the release liner 18 or layer of adhesive 16. Optionally, a second release liner (not shown) may be then applied to

electrically conductive adhesive 24. The electrode is utilized by after first removing the release liner from electrically conductive adhesive 24 if any, applying the biomedical electrode to the body with electrically conductive adhesive 24. Protective web 12 may then be lifted and release liner 18 removed. Lead wire 14 is then inserted into the located where release liner 18 was removed and protective web 12 is secured over lead wire 14. The conductor plate 30 part of the noninsulated portion 26 of lead wire 14 is held in place by adhesive 15 and makes electrical contact with electrically conductive film 22. Insulative portion 28 of lead wire 14 is contained under the edge of protective web 12 in order to have a completely insulated biomedical electrode 10E system.

The biomedical electrode 10F illustrated in Figure 8 is similar to the biomedical electrode 10D illustrated in Figure 6. Biomedical electrode 10F has a top layer consisting of a protective electrically insulative web 32 which in a preferred embodiment is an electrically insulative plastic sheet. The bottom side of protective web 32 is coated with an electrically conductive metallic coating 34 which in a preferred embodiment is aluminum which has been vapor coated onto the protective web 32 preferably in thicknesses of from 700 to 1200 angstroms. A release liner 18 with the release agent facing downward is positioned adjacent to the metallic coating 34 and covers a portion of the surface area of the biomedical electrode 10F. An electrically conductive adhesive 24 of the same type as described in Figure 2 is then located below release liner 18 and is directly attached to release liner 18 or metallic coating 34. In use, biomedical electrode 10F may be applied to the body by electrically conductive adhesive 24. Release liner 18 may be removed and an electrical lead wire (not shown) may be inserted in place of the release liner 18. Once the electrical lead wire is placed, the protective web 32 may be resecured over the top of the electrical lead wire. Electrically conductive adhesive 24 holds both the electrical lead wire and protective web 32 in place. Metallic coating 34 over the lower surface of protective 32 helps distribute the electrical current supplied from or to the electrical lead wire over the entire surface area of biomedical electrode 10F. In a preferred embodiment, protective web 32 with metallic coating 34 and release liner 18 extend beyond one edge of electrically conductive adhesive 24 so that they may be easily grasped to facilitate easy removal of release liner 18 when required.

Although biomedical electrode 10 has been illustrated as being in generally rectangular shaped it is to recognized and understood that any suitable shape, size or configuration of biomedical electrode 10 may be utilized to fit or suit the particular environment or body part to which it is adapted to be applied.

Figures 9 and 10 illustrate the basic construction of the biomedical electrode 110 of the present invention. A protective web 112 is applied by a pressure-sensitive adhesive 114 to a backing material 116. A removable release liner 118 is positioned between the protective web 112 and its associated pressure-sensitive adhesive 114 and backing material 116. Backing material 116 contains an aperture 120 which the protective web covers. An electrical lead wire 122 having a conductive portion 124 and an insulative portion 126 is insertable into the biomedical electrode with the conductive portion 124 of lead wire 122 positioning itself within aperture of backing material 116. Although not absolutely required, it is preferred that lead wire 122 have an insulative portion 126 such that when the conductive portion of lead wire 122 is positioned within aperture 120 and covered with protective web 112 only the insulated portion 126 of lead wire 122 is exposed. An electrically conductive adhesive 128 is located on the backing material 116 below aperture 120. The electrically conductive adhesive 128 positioned in this manner will contact the conductive portion 124 of lead wire 122 when the lead wire is inserted into aperture 120. A second removable liner 130 is positioned below electrically conductive adhesive 128 to be removed before the biomedical electrode 110 is applied to the body. It is only necessary that electrically conductive adhesive 128 be positioned under aperture 120 in backing material 116. Electrically conductive adhesive 128, of course, could cover the entire surface area of backing material 116. Electrically conductive adhesive 128, of course, could cover the entire surface area of backing material 116. If this were the case, no other adhesive in the biomedical electrode would be required. However, since electrically conductive adhesives may be more expensive than other adhesives. In a preferred embodiment, electrically conductive adhesive 128 covers only the general area of backing material 116 which is under aperture 120. Another pressure-sensitive adhesive 132 is then applied to the remainder of the surface area of backing material 116 to enable the biomedical electrode to be secured to the body when it is utilized. Alternatively, pressure-sensitive adhesive 132 could be applied to the entire surface area of backing material 116 and the portion under aperture 120 would be removed when aperture 120 was cut into backing material 116.

Although shown in generally rectangular shape, biomedical electrode 110 by appropriate sizing or trimming of backing material 116 may be any appropriate shape desired in order to conform or be located in any particular spot on the body. Aperture 120 is shown circular in nature and central within backing member 116 neither is absolutely required. Aperture 120 could, for example, be elongated to more

appropriately conform to the conductive portion 124 of lead wire 122 and need to be centrally located within the backing material 116. As illustrated, protective web 112 covers generally only the area of backing material 116 over aperture 120. In other embodiments, protective web 112 could, of course, cover more of the surface area of backing material 116 for the entire surface area of backing material 116, if desired.

In a preferred embodiment, protective web 112 is electrically insulative to confine the electrical signals used in the biomedical electrode 110 to the lead wire 122 or to the body. In a preferred embodiment, protective web 112 is approximately 2 mils (0.51 millimeters) thick and is preferably constructed from polyester film. Pressure sensitive adhesive 114 is preferably an acrylate adhesive. Release liner 118, which is removable, facilitates the lifting of protective web 112 away from backing material 116 in order to lead wire 122 may be inserted and protective web 112 subsequently applied securing a conductive portion 124 of lead wire 122 and the biomedical electrode 110. In a preferred embodiment, release liner 118 is a Polyslick material as manufactured by James River Corporation, H.P. Smith Division, Bedford Park, Illinois.

Backing material 116 may be constructed from any generally flat, body conformable, flexible material. In a preferred embodiment, backing material 116 is a foam material, and in a more preferred embodiment is a polyethylene foam, for example, a 0.003 inches thick polyethylene foam. Lead wire 122 may be copper wire whose insulative portion 126 is insulated with any suitable insulation as, for example, rubber or plastic. The conductive portion 124 of lead wire 122 may be a flat crimped conductor plate 130. Conductor plate 130 is flat which facilitates the biomedical electrode 110 being of low profile, flat and conformable to the body. In most preferred embodiments of the biomedical electrode 110, the conductive portion 124 of lead wire 122 should be silver or silver plated and preferably have a chloride treatment. Conductive adhesive 128 operates to secure the biomedical electrode 110 to the body and to provide through electrical conductivity from the body to the biomedical electrode. It is preferred that conductive adhesive 128 have better cohesion than adhesion in order to facilitate the ease with which the biomedical electrode 110 may be removed from the body. In a preferred embodiment, conductive adhesive 128 is a conductive adhesive as described in U.S. Patent No. 4,554,924, Engel, Conductive Adhesive and Biomedical Electrode. Removable release liner 130 may also be Polyslick liner. Pressure sensitive adhesive 132 is also an acrylate adhesive.

Figure 11 illustrates the biomedical electrode 110 having been applied to a body 134. Lead wire 122 is shown being secured in the biomedical electrode 110 by protective web 112, its associated pressure-sensitive adhesive 114 (not shown) and the electrically conductive adhesive 128 (not shown) to which it contacts. Backing material 116 is secured to the body with electrically conductive adhesive 128 (not shown) and pressure-sensitive adhesive 132 (not shown). When this particular use for the biomedical electrode has been completed, protective web 112 may be pulled back releasing lead wire 122 from the biomedical electrode 110 allowing the reuse of lead wire 122 and another biomedical electrode 110. Since there are no silver components to the biomedical electrode except for the silver plating or silver containment of conductive portion 124 lead wire 122 and since the lead wire 122 may be reused many times, an economical biomedical electrode 110 is provided. Biomedical electrode is flatter and more conformable to the body contours and body movement than prior art electrodes. The biomedical electrode 110 relies on adhesive contact with a flat electrical conductor as opposed to rubber connector strips or snaps. The biomedical electrode 110 has a very low profile which makes it suitable to be worn under tight clothing and to be comfortable when slept upon or when leaned against as, for example, when sitting in a chair. The biomedical electrode 110 may be trimmed to virtually any size or shape to allow flexibility and adaptability in placement and location upon the body.

Thus, it can be seen that there has been shown and described a novel, flat, conformable, biomedical electrode. It is to be recognized and understood, however, that various changes, modifications and substitutions in the form and of the details of the present invention can be made by those skilled in the art without departing from the scope of the invention as defined by the following claims.

Claims

1. A biomedical electrode adapted to be applied to a body and adapted to be electrically and mechanically connected to an electrical leadwire, comprising:

a protective, electrically insulative web;

an electrically conductive adhesive adjacent to one side of said protective, insulative web, said one side adapted to be oriented toward said body; and

a release liner between said protective, electrically insulative web and said electrically conductive adhesive, said release liner having a release agent facing said conductive adhesive, said release liner covering only a portion of the surface area of said protective, electrically insulative web.

2. A biomedical electrode as in claim 1 which further comprises a pressure sensitive adhesive between said release liner and said protective, electrically insulative web.

3. A biomedical electrode as in claim 1 which further comprises an additional release liner placed adjacent said electrically conductive adhesive opposite said protective, electrically insulative web.

4. A biomedical electrode adapted to be applied to a body, comprising:

a protective, electrically insulative web;

an electrically conductive adhesive adjacent one side of said protective, insulative web, said one side adapted to be oriented toward said body;

a removable release liner between said protective, electrically insulative web and said electrically conductive adhesive, said release liner having a release agent facing said conductive adhesive, said release liner covering only a portion of the surface area of said protective, electrically insulative web; and

an insertable electrical lead wire having a distal uninsulated portion and a proximate insulated portion, said distal uninsulated portion of said electrical lead wire being insertable between said conductive adhesive and said protective, electrically insulative web and at least part of said proximate insulated portion of said electrical lead wire extending under an edge of said protective, electrically insulative web.

whereby said removable release liner may be discarded, said insertable electrical lead wire may be positioned, said protective, electrically insulative web may be secured over said uninsulated portion of said electrical lead wire and secured in place by said electrically conductive adhesive.

5. A biomedical electrode adapted to be applied to a body and adapted to be electrically and mechanically connected to an electrical lead wire, comprising:

a protective, electrically insulative web;

a first layer of adhesive adjacent one side of said protective, electrically insulative web, said one side adapted to be oriented toward said body;

a release liner adjacent said first layer of adhesive and opposite said protective, electrically insulative web, said release liner having a release agent facing said first layer of adhesive, said release liner covering only a portion of the surface area of said protective, electrically insulative web;

a second layer of adhesive which is electrically conductive and positioned adjacent said release liner opposite from said protective, electrically insulative web;

an electrically conductive film positioned adjacent said second layer of adhesive opposite said release liner; and

a third layer of adhesive which is electrically conductive and positioned adjacent said electrically conductive film opposite said second layer of conductive adhesive and adapted to be applied to said body.

6. A biomedical electrode as in claim 5 wherein said electrically conductive film has a metallic coating on said self-supporting, conductive film.

7. A biomedical electrode as in claim 6 which further comprises a pressure sensitive adhesive between said release liner and said protective, electrically insulative web.

8. A biomedical electrode as in claim 5 which further comprises an additional release liner placed adjacent said electrically conductive adhesive opposite said protective, electrically insulative web.

9. A biomedical electrode adapted to be applied to a body, comprising:

a protective, electrically insulative web;

a first layer of adhesive adjacent one side of said protective, electrically insulative web, said one side

adapted to be oriented toward said body;

a removable release liner adjacent said first layer of adhesive opposite from said protective, electrically insulative web, said release liner having a release agent facing said first layer of adhesive, said release liner covering only a portion of the surface area of said protective, electrically insulative web; and

a second layer of adhesive which is electrically conductive and positioned adjacent said release liner opposite from said protective, electrically insulative web;

an electrically conductive film positioned adjacent said second layer of adhesive opposite said release liner;

a third layer of adhesive which is electrically conductive and positioned adjacent said electrically conductive film opposite said second layer of adhesive and adapted to be applied to said body; and

an insertable electrical lead wire having a distal uninsulated portion and a proximate insulated portion, said distal uninsulated portion, of said electrical lead wire being insertable between said first layer of adhesive and said second layer of adhesive and at least part of said proximate insulated portion of said electrical lead wire extending under an edge of said protective, electrically insulative web;

whereby said removable release liner may be discarded, said insertable electrical lead wire may be positioned, said protective, electrically insulative web may be secured over said uninsulated portion of said electrical lead wire and secured in place by said first layer of adhesive and said second layer of adhesive.

10. A biomedical electrode adapted to be applied to a body and adapted to be electrically and mechanically connected to an electrical lead wire, comprising:

a protective, electrically insulative web;

a first layer of adhesive adjacent one side of said protective, electrically insulative web, said one side adapted to be oriented toward said body;

a release liner adjacent said first layer of adhesive and opposite said protective, electrically insulative web, said release liner having a release agent facing said first layer of adhesive, said release liner covering only a portion of the surface are of said protective, electrically insulative web;

an electrically conductive film positioned adjacent said first layer of adhesive and said release liner; and

a second layer of adhesive which is electrically conductive and positioned adjacent said electrically conductive film opposite said first layer of adhesive and adapted to be applied to said body;

an insertable electrical lead wire having a distal uninsulated portion and a proximate insulated portion, said distal uninsulated portion of said electrical lead wire being insertable between said first layer of adhesive and said electrically conductive film and at least part of said proximate insulated portion of said electrical lead wire extending under an edge of said protective, electrically insulative web.

11. A biomedical electrode as in claim 10 wherein said electrically conductive film has a metallic coating on said self-supporting, conductive film.

12. A biomedical electrode adapted to be applied to a body and adapted to be electrically and mechanically connected an an electrical lead wire comprising:

a protective, electrically insulative web;

an electrically conductive metallic coating applied to one side of said protective, electrically insulative web, said one side adapted to be oriented toward said body;

a release liner adjacent said metallic coating having a release agent facing away from said metallic coating, said release liner covering only a portion of the surface area of said protective, electrically insulative web; and

a layer of an electrically conductive adhesive covering said release liner in said portion of the surface area which contains said release liner and covering said metallic coating over the remainder of the surface area;

whereby said biomedical electrode may be applied to sidebody with said electrically conductive adhesive contacting said body, said release liner may be removed and said suitable electrical lead wire may be inserted in place of said release liner and said protective web may be secured over said electrical lead wire.

13. A biomedical electrode adapted to be applied to a body, comprising:

a backing material having an aperture, having a top side adapted to be oriented away from said body and having a bottom side adapted to be oriented toward said body;

a protective web at least partially secured to said top side of said backing material and covering said aperture;

a first removeable liner positioned between said protective web and said foam backing, said first removeable liner covering at least a portion of the area of said foam backing covered by said protective web and covering said aperture;

an electrically conductive adhesive positioned adjacent said backing material on said bottom side of said backing material covering said aperture;

a second removeable liner positioned adjacent said electrically conductive adhesive opposite from said foam backing; and

a lead wire having one end adapted to be positioned within said aperture from said top side of said foam backing so as to be adhered to said electrically conductive adhesive;

whereby said second removeable liner may be removed and said biomedical electrode may be applied to said body with said electrically conductive adhesive and whereby said first removeable liner may be removed and said lead wire may be positioned with said one end within said aperture and secured by said protective web.

14. A biomedical electrode as in claim 13 wherein said backing material comprises a foam material.

15. A biomedical electrode adapted to be applied to a body, comprising:

a backing material having an aperture, having a top side adapted to be oriented away from said body and having a bottom side adapted to be oriented toward said body;

a first layer of adhesive adjacent said top side of backing material;

a protective web adjacent said first layer of adhesive at least partially securing said protective web to said top side of said backing material and covering said aperture;

a first removeable liner positioned between said protective web and said foam backing, said first removeable liner covering at least a portion of the area of said backing material covered by said protective web and covering said aperture;

an electrically conductive adhesive positioned adjacent said foam backing on said bottom side of said backing material covering said aperture;

a second removeable liner positioned adjacent said electrically conductive adhesive opposite from said backing material; and

a lead wire having one end adapted to be positioned within said aperture from said top side of said backing material;

whereby said second removeable liner may be removed and said biomedical electrode may be applied

to said body with said electrically conductive adhesive and whereby said first removeable liner may be removed and said lead wire may be positioned with said one end within said aperture and secured by said protective web.

16. A biomedical electrode as in claim 15 wherein said backing material comprises a foam material.

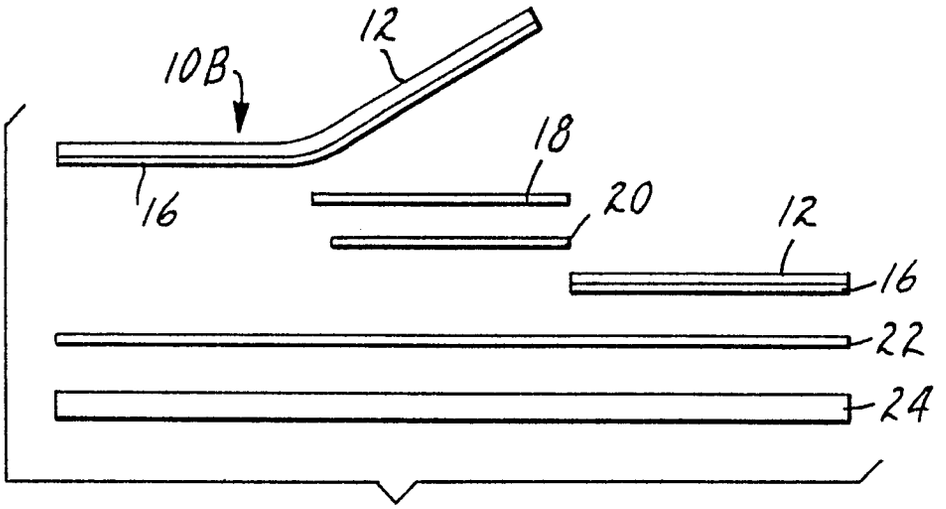

FIG. 4

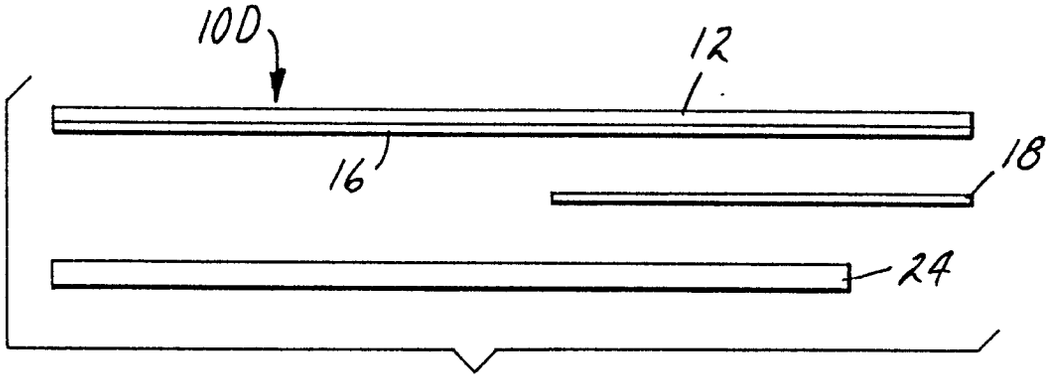

FIG. 6

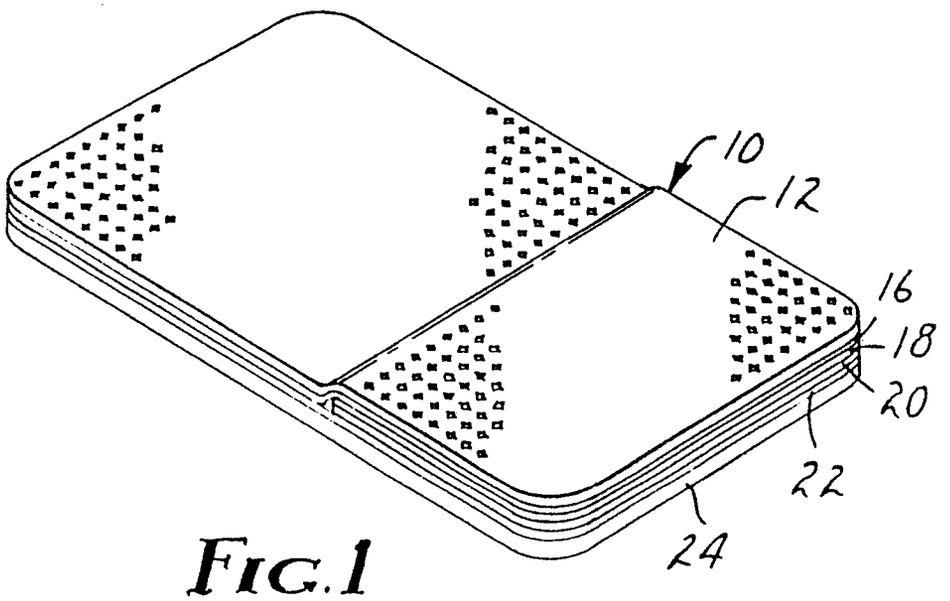

FIG. 1

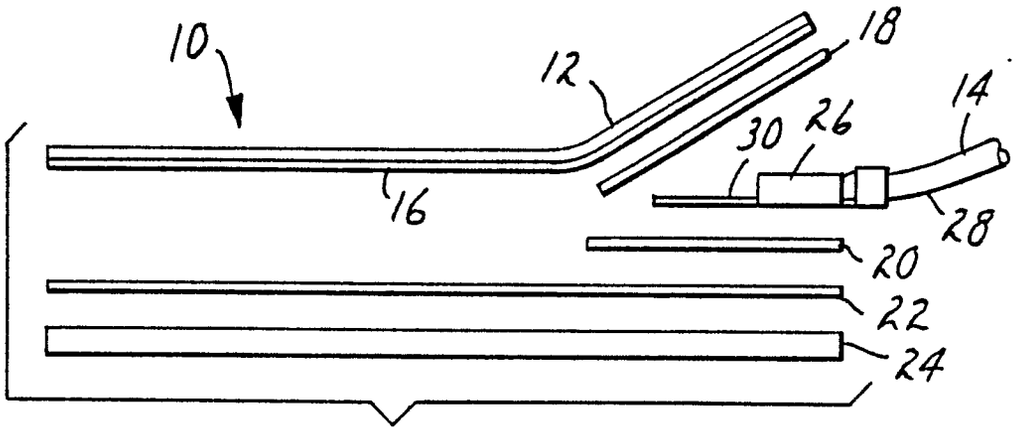

FIG. 2

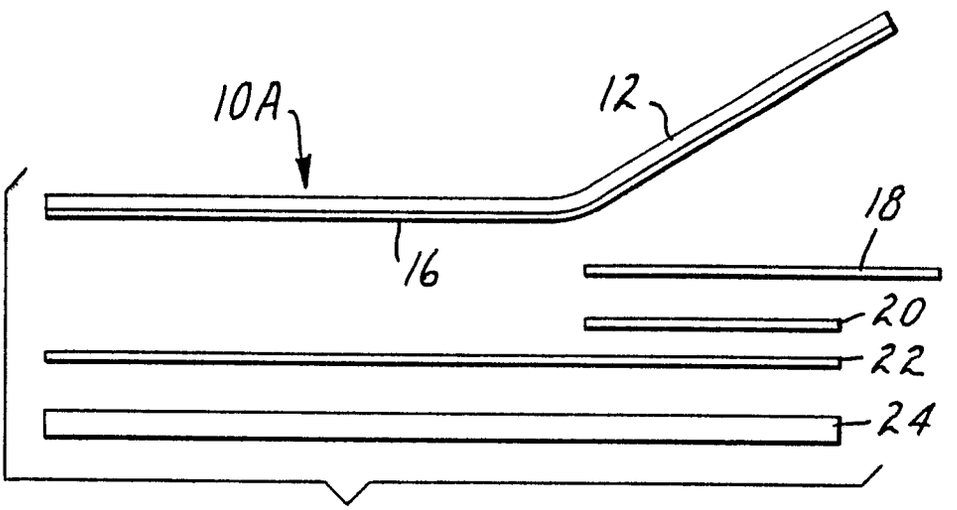

FIG. 3

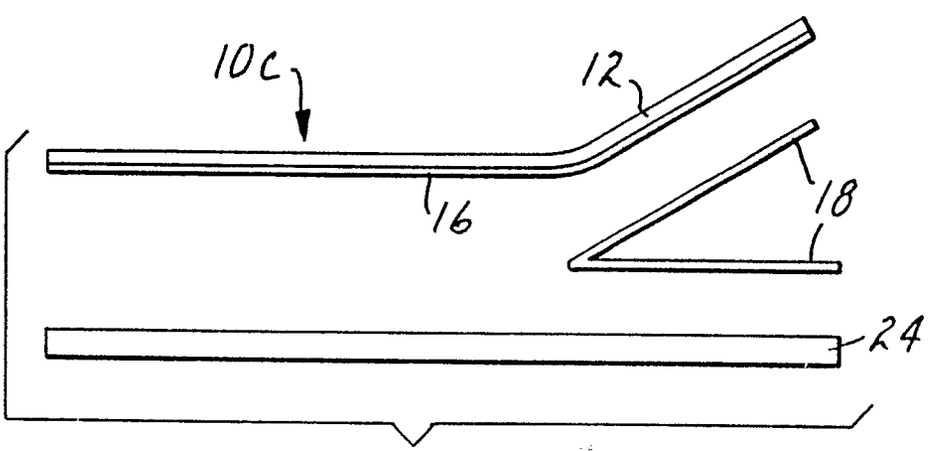

FIG. 5

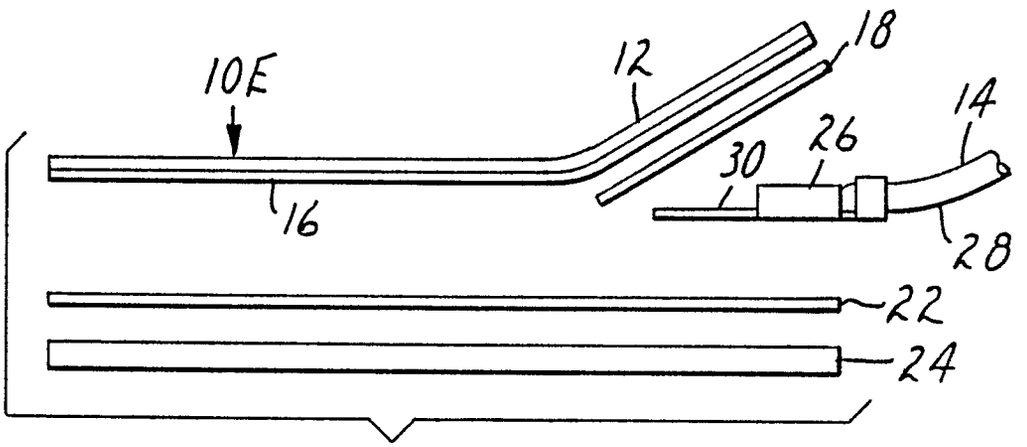

FIG. 7

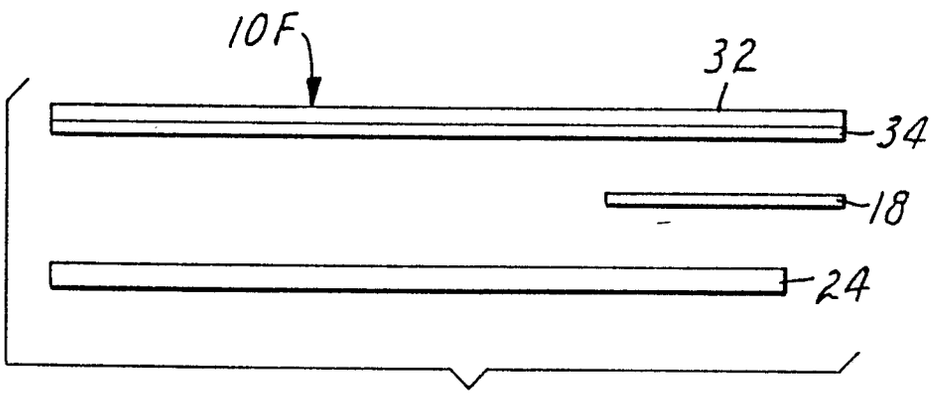

FIG. 8

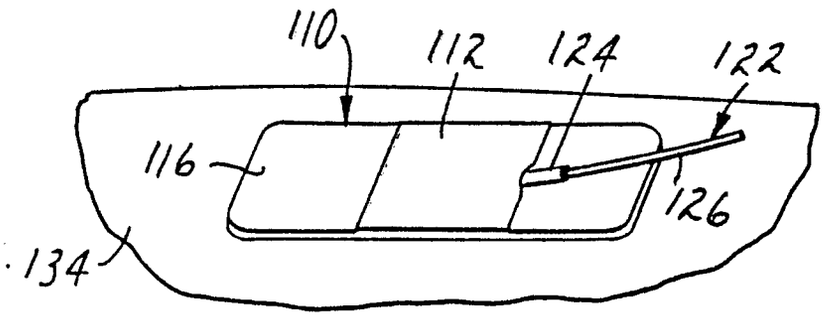

FIG. 11

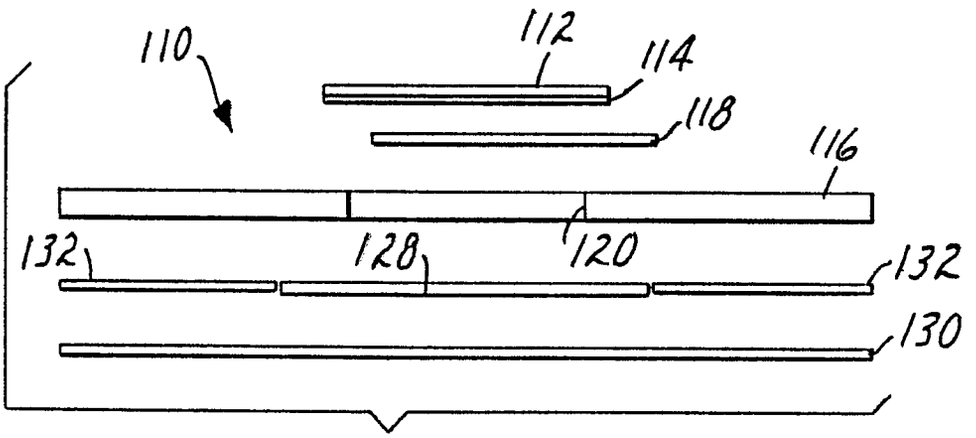

FIG. 10

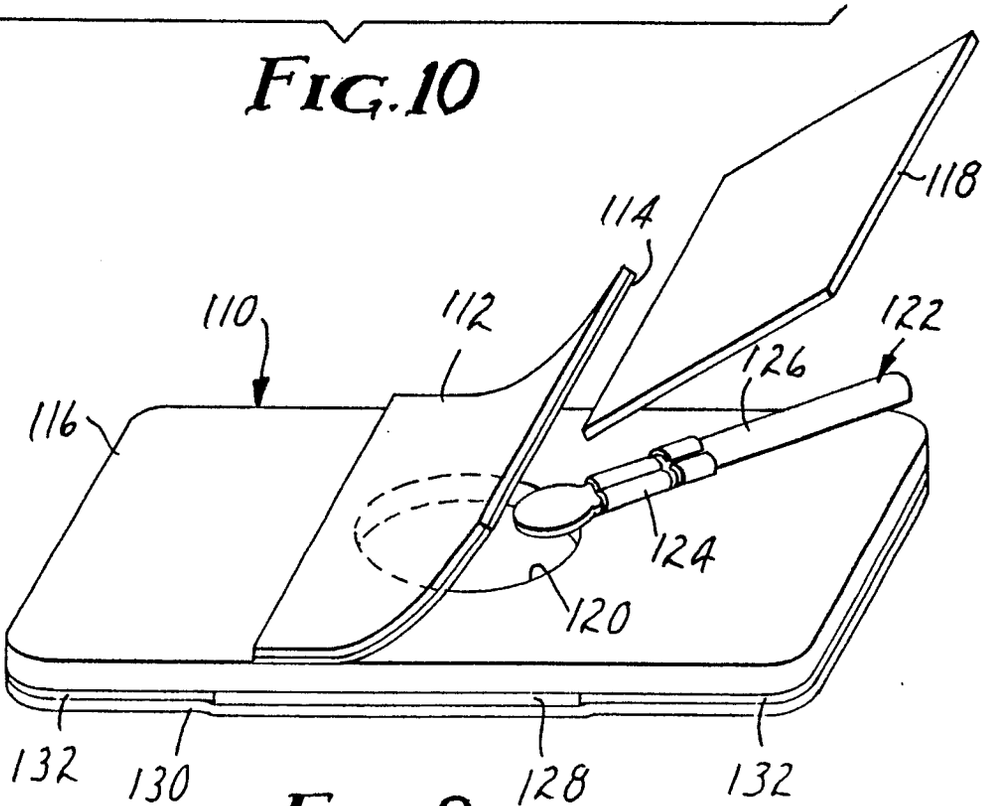

FIG. 9

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 87 30 6810

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	FR-A-1 470 698 (GENERAL ELECTRIC CO.) * page 1, right-hand column, line 2 - page 2, right-hand column, line 11; figures 1-3 *	1-4	A 61 B 5/04 A 61 N 1/04
A	US-A-4 524 775 (J. RASMUSSEN) * column 3, lines 9-50; figures 1, 2 *	1	
A	EP-A-0 097 436 (MINNESOTA MINING AND MANUFACTURING CO.) * page 4, line 17 - page 6, line 17; figures 1, 2 *	10-15	
			TECHNICAL FIELDS SEARCHED (Int. Cl.4)
			A 61 B 5/00 A 61 N 1/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	02-11-1987	WEIHS J.A.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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